



6450-01-P

DEPARTMENT OF ENERGY

Notice of Intent to Withdraw from Production and Distribution of the Radioisotope Germanium-68 Used for Calibration Sources

AGENCY: Office of Science, Department of Energy.

ACTION: Notice of Intent and Request for Comment.

SUMMARY: The Isotope Program of the Office of Science of the Department of Energy (Department or DOE) currently produces and distributes the radioisotope germanium-68 (Ge-68). There are two primary uses of the Ge-68: in the manufacture of calibration sources for Positron Emission Tomography (PET) scanners used for diagnostic medical imaging; and in the manufacture of germanium-68/gallium-68 (Ge-68/Ga-68) generators, which provide Ga-68 as a positron source in radiopharmaceuticals used in PET imaging.

The Department published in the **Federal Register** on March 8, 2013, a Notice of Inquiry and Request for Comment on its consideration of withdrawal from commercial production of Ge-68. The Department received numerous comments in response to this Notice of Inquiry, evaluated substantial information provided by one private domestic company seeking the Department's withdrawal, and assessed other information in reaching its conclusion. The Department has determined that Ge-68 is reasonably available from the commercial sector for use in the manufacture of calibration sources but not for use in Ge-68/Ga-68 generators. This Notice of Intent provides the public with notice and seeks any public comment on the Department's intent to withdraw from the production and distribution of Ge-68 used in the manufacture of calibration sources, while maintaining its current position in the production and distribution of

Ge-68 for Ge-68/Ga-68 generators. The Department intends to ramp down its sales of Ge-68 to calibration source fabricators and such sales will end completely April 30, 2014. After that date, the Department's customers will be required to sign an end-use statement that the Ge-68 will be used in the fabrication of Ge-68/Ga-68 generators.

DATES: Interested persons must submit written comments by May 9, 2014.

ADDRESSES: Comments may be submitted by mail to: Dr. Marc Garland, Program Manager, Office of Nuclear Physics, Office of Science, U.S. Department of Energy, Germantown Building, SC-26.2, 1000 Independence Ave., SW., Washington, DC 20585-1290, or electronically by email to: marc.garland@science.doe.gov. We note that email submissions will avoid delay associated with security screening of U.S. Postal Service mail.

FOR FURTHER INFORMATION CONTACT: Dr. Jehanne Gillo, Director Facilities and Project Management Division, Office of Nuclear Physics, Office of Science, U.S. Department of Energy, Germantown Building, SC-26.2, 1000 Independence Ave., SW, Washington, DC 20585, Tel: 301-903-1455.

SUPPLEMENTARY INFORMATION:

It is the Department's policy to refrain from competition with private industry in the commercial production and distribution of radioisotopes when those radioisotopes are reasonably available commercially. This policy was announced in the Notice published in the **Federal Register** in 1965, entitled Policies and Procedures for Transfer of Commercial Radioisotope Production and Distribution to Private Industry ("Statement of Policy"), 30 FR 3247 (March 9, 1965). The Statement of Policy provides criteria and guidance on withdrawal

from the market and states that when the Department determines to voluntarily withdraw from the commercial production and distribution of particular radioisotopes, it will publish a notice of such intent for public comment.

Background

The Department currently produces and distributes the radioisotope Ge-68. Recently, it was made aware of domestic private industry development of commercial production and distribution of this radioisotope in the United States, in addition to the distribution in the United States of the radioisotope produced by foreign entities. In light of these circumstances, a Notice of Inquiry and Request for Comment entitled Consideration of Withdrawal from Commercial Production and Distribution of the Radioisotope Germanium-68 (“Notice of Inquiry”) was published in the **Federal Register** (78 FR 15009, March 8, 2013) announcing the Department’s intent to conduct an evaluation and to request comments and information from the public for consideration in the evaluation. In summary, the Department’s evaluation included consideration of: a demonstrable private capability to produce and distribute Ge-68; effective competition in the market for the production and distribution of Ge-68; assurance that private industry will not discontinue production or distribution of Ge-68 in a manner that would adversely impact the public interest; the Ge-68 will be available at reasonable prices consistent with its intended uses and the prices to be charged will also encourage further research and development; and comments and information from the public received in response to the Notice and Departmental inquiries.

Evaluation and Determination

The Department received numerous comments in response to the Notice of Inquiry from private citizens affected by the use of Ge-68 in Ge-68/Ga-68 generators critical in medical imaging for certain cancers, and from some private companies involved in the manufacture of products for medical purposes. Responses from commenters focused on concerns such as pricing, monopolies, and discontinuation of isotope availability in the event of foreign or domestic supply disruption. A private U.S. company, Mallinckrodt Pharmaceuticals Inc., supplied a substantial amount of information in support of the Department's withdrawal from commercial production and distribution of Ge-68. The concerns and interests expressed by private citizens and affected industry are precisely those which comprise the factors the Department has evaluated to ensure there would be no adverse impacts in the event of DOE withdrawal from production.

While DOE is currently the only domestic producer of Ge-68, there are foreign producers of Ge-68 that distribute the radioisotope in the U.S. through U.S. distributors. Mallinckrodt has an existing facility in the U.S. that currently produces radioisotopes, with the capability to produce Ge-68 for domestic distribution. The information supplied by Mallinckrodt indicates it has a long history as a strong market participant in the production and sales of radioisotopes. Further, Mallinckrodt was judged to have the facilities, expertise, and management and financial resources necessary to produce sufficient quantities of Ge-68 to meet domestic demand. Production and distribution of radioisotopes is the core of the Mallinckrodt's business and Ge-68 is the latest product that they have developed to generate near-term sales and

capture a share of a long-term growth market. Mallinckrodt has demonstrated capability to commercially produce Ge-68.

The Department has determined that there is sufficient evidence to conclude that, upon the Department's withdrawal from the production and distribution of Ge-68, Mallinckrodt would continue production of Ge-68, based upon the investments it's made in developing production capability, the fact that it has built a worldwide capability to engage in isotope production and distribution, and that such activities are at the core of their business. The Department has further concluded that if it were to withdraw from the market, Mallinckrodt would establish the price for the Ge-68 isotope on a fair and reasonable basis and within a range of the prices the Department currently charges. While Mallinckrodt did not explicitly state the price it would charge, its intention to maintain pricing consistent with the market suggests that there would not be catastrophic price changes if the Department withdraws from the market. With multiple private sector suppliers, pricing more likely than not would be controlled by market forces obviating the need for any Department mandate.

In light of the information provided by Mallinckrodt, input from private industry, and other information available to the Department, the Department intends to withdraw from the market for Ge-68 for the manufacture of PET calibration sources. The Department has concluded that Mallinckrodt has the capability and intent to meet market demand, and because there are multiple suppliers of Ge-68 suitable for use in the manufacturing of PET calibration sources (as well as multiple companies engaging in source fabrication), the Department has further

concluded that the demand for the Ge-68 for calibration source manufacturing will be met and maintained at reasonable market-based pricing.

The Department has concluded that it will not withdraw from the market for Ge-68 for the manufacture of generators, however, because it has determined that there are no suppliers of bulk Ge-68 qualified for use in Ge-68/Ga-68 generators. This issue involves several concerns. First, if the Department were to exit the market, it appears that there would be no domestic producers of Ge-68 presently qualified for use in Ge-68/Ga-68 generators. These generators provide Ga-68 which is incorporated as a positron source in radiopharmaceuticals used in PET imaging medical applications currently under development. Qualification of other Ge-68 suppliers to serve the generator market would take time (in addition to potentially lengthy product testing, producers may have to change their production processes to provide Ge-68 that can be used on a generator for Ga-68 use in humans) and could impact researchers' achievement of Food and Drug Administration (FDA) approval for Ga-68-based medical imaging. Second, there is only one known foreign supplier of Ge-68/Ga-68 generators, which the Department does not believe is a dependable supply source for the U.S. market. The foreign supplier's production data does not provide adequate assurance the U.S. generator market would be adequately supplied by foreign suppliers. In the absence of a Department supply of Ge-68 for the manufacture of generators, Mallinckrodt would be the only immediate domestic source for generators, but only when or if the Mallinckrodt develops its own generator or its Ge-68 is qualified for use by other generator manufacturers. A single foreign supplier represents a risk that one domestic company, Mallinckrodt, could be the sole reliable domestic supplier of Ge-68 for generators and this could be problematic for the U.S. market for

generators. If generator manufacturers were able to qualify Mallinckrodt's Ge-68 for use in generators, the Department's withdrawal from production would provide Mallinckrodt with a monopoly position in the marketplace for Ge-68 use in the manufacture of generators and other generator manufacturers would eventually be in a position of having to buy Ge-68 from their competitor.

In light of these circumstances, the Department has concluded that there is not effective competition in the market for Ge-68 for use in Ge-68/Ga-68 generators, and therefore it will continue to serve that segment of the Ge-68 market to provide competition. The Department's participation in that segment of the market will serve to reduce the potential for impediments to research and development leading to FDA approval of Ga-68 radiopharmaceuticals.

To help provide assurance of supply of Ge-68 for calibration source purposes, DOE proposes to maintain production capability, but not engage in sales to the marketplace, such that production would resume in a timely manner if Mallinckrodt and other suppliers are not be able to adequately serve the market or if private supplier pricing substantially increases and has a negative impact on the development and utilization of Ge-68 products.

Issued in Washington, DC on April 2, 2014.

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Office of Science

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